

K092425

SECTION 5: 510(k) SUMMARY

Submitter: Ascent Healthcare Solutions
10232 South 51st Street
Phoenix, Arizona 85044

Contact: Amanda Babcock
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OCT 21 2009

Date of preparation: August 5, 2009

Name of device: *Trade/Proprietary Name:* Reprocessed 3D Diagnostic
Ultrasound Catheters
Classification Name: Catheter, Angiography, Reprocessed

Predicate Device K070242	510(k) Title SOUNDSTAR™ 3D Ultrasound Catheter, Model M-5723-05	Manufacturer Biosense Webster, Inc.
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Device description: 3D Diagnostic Ultrasound Catheters are specially designed catheters that provide two-dimensional imaging using an ultrasound transducer and three-dimensional location information using a location sensor. The ultrasound transducer and location sensor are at the distal tip of the catheter and can be positioned for ultrasound imaging and 3D mapping by a steering mechanism that rotates the catheter tip and variable deflection. 3D Diagnostic Ultrasound Catheters incorporate a handpiece, a flexible shaft and a distal tip section containing an ultrasound transducer and a location sensor. The SOUNDSTAR™ 3D Diagnostic Ultrasound Catheter 3-D location sensor provides location information to the CARTO® XP EP Navigation System (mapping system). The SOUNDSTAR™ 3D Diagnostic Ultrasound Catheter is 10 French with a 90 cm insertion length.

Indications for Use: Reprocessed 3D Diagnostic Ultrasound Catheters are indicated for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The 3D Diagnostic Ultrasound Catheter provides location information when used with the CARTO® XP EP Navigation System Version 9 or greater.

Technological characteristics: The SOUNDSTAR™ 3D Diagnostic Ultrasound Catheter is a 90cm 10F IntraCardiac diagnostic ultrasound catheter with an acoustic array identical to the ACUSON AcuNav 10F Diagnostic Ultrasound Catheter. The catheter has a location sensor (providing location information to the CARTO® EP XP

Navigation System) and an ultrasound transducer (acquiring real time ultrasound images) embedded in the tip. It also has a pre-amplifier circuit board inside the handle that amplifies the signals from the location sensor. The location sensor consists of a set of three micro-machined coils that act as pick up coils when placed in an external electromagnetic field created by external field generator coils. The sensor coils are positioned orthogonal to each other inside the sensor assembly. The coils pick up signals from the field in response to their position and orientation with respect to a frame of reference. The signals are processed by a system to calculate the position and orientation of the tip of the catheter. The associated circuitry for the sensor consists of pre-amplifier circuits for each coil.

Performance data: Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed 3D Diagnostic Ultrasound Catheters. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed 3D Diagnostic Ultrasound Catheters perform as originally intended.

Conclusion: Ascent Healthcare Solutions concludes that the modified devices (Reprocessed 3D Diagnostic Ultrasound Catheters) are safe, effective, and substantially equivalent to the predicate devices as described herein.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ascent Healthcare Solutions
c/o Ms. Amanda Babcock
Regulatory Affairs Specialist
10232 South 51st Street
Phoenix, AZ 85044

OCT 21, 2009

Re: K092425
Trade/Device Name: Reprocessed 3D Ultrasound Catheter (See Enclosed Model)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II (two)
Product Code: NLI
Dated: August 5, 2009
Received: August 7, 2009

Dear Ms. Babcock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

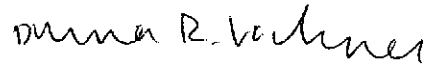
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Original model found to be SE
SOUNDSTAR™ 3D Ultrasound Catheter, Model M-5723-05

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K092425

Device Name: Reprocessed 3D Diagnostic Ultrasound Catheters

Indications For Use:

Reprocessed 3D Diagnostic Ultrasound Catheters are indicated for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The 3D Diagnostic Ultrasound Catheter provides location information when used with the CARTO® XP EP Navigation System Version 9 or greater.

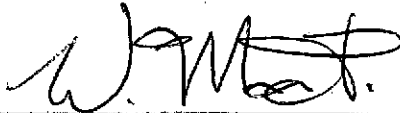
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092425